

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

MAR - 4 2010

Establishment:

- Address: Siemens AG, Medical Solutions
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Device Name and Classification:

- Trade Name: *syngo.plaza*
Classification Name: Picture Archiving and Communications System
- Classification Panel: Radiology
- CFR Section: 21 CFR §892.2050
- Device Class: Class II
- Product Code: LLZ

Date of Submission:

November 06, 2009

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

• Device Description and Intended Use:

This premarket notification covers Siemens' enhanced PACS system *syngo.plaza*.

syngo.plaza is a Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital medical images.

It supports the physician in diagnosis and treatment planning.

syngo.plaza also supports storage and archiving of DICOM Structured Reports.

In a comprehensive imaging suite *syngo.plaza* integrates Hospital/Radiology Information Systems (HIS/RIS) to enable customer specific workflows. *syngo.plaza* optionally uses a variety of advanced post processing applications.

Note:

Web-based image distribution is not intended for reporting.

In the U.S.A., *syngo.plaza* is not intended for the reporting of digital mammography images.

syngo.plaza Workplaces

The three *syngo.plaza* workplace deployments ...

- a) *syngo.plaza* Cluster Client
- b) *syngo.plaza* Web Client
- c) *syngo.plaza* Standalone Workstation

... are medical diagnostic and viewing workstations intended for post processing, reading, reporting, viewing and communicating / distributing of radiological softcopy images and so allow radiologists and radiological technicians to receive and process all data needed.

By usage of only specific FDA approved monitors validated together with the software, diagnosis on digital mammography images is possible, but it is not supported in the U.S.A. as disclaimed in the Intended Use.

Integration

The integration of *syngo.plaza* shall be applied at different levels and by using technologies like sharing the same HW/SW platform, using common Siemens Medical components (e.g. OPENLink), offering an open interface for other vendors to connect with other DICOM nodes and especially the DICOM Archive functionality, with other information systems (mainly RIS).

• **Technological Characteristics:**

syngo.plaza is a "software only"-system, which will be delivered on CD-ROM / DVD or also preconfigured on hardware. *syngo.plaza* will be installed by Siemens service engineers.

Defined Hardware requirements are to be met.

The herewith described *syngo.plaza* supports DICOM formatted images and objects.

• **Summary of Non-Clinical Testing:**

The software verification and validation (Unit Test Level, Integration Test Level and System Test Level) was performed for all newly developed components and the complete system according the following standards:

- DICOM Standard [2008]
- JPEG/JPEG 2000 Standard [1992, 2002]
- SMPTE Test Pattern [1995]
- ISO 14971:2007
- IEC 60601-1-4 + A1 [1999]
- IEC 60601-1-6 [2006]

- HL7 [2006]
- IEC 62304 [2006]

After completion of the system test and comparison of the test results with the software release acceptance criteria, Siemens is of the opinion, that *syngo.plaza* is substantially equivalent to and performs as well as the predicate device.

- **General Safety and Effectiveness Concerns:**

The device labelling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing.

- **Substantial Equivalence:**

The *syngo.plaza*, addressed in this special premarket notification, is substantially equivalent to the following commercially available device:

Siemens	<i>syngo</i> Imaging XS V70	K082430
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The *syngo.plaza* described in this 510(k) has the same intended use and similar technical characteristics as the device listed above in regard to the specific functionalities. In summary, Siemens is of the opinion that *syngo.plaza* does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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NEW BRIGHTON MN 55112-1891

MAR - 4 2010

Re: K093612
Trade/Device Name: *syngo*, plaza
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 10, 2010
Received: February 16, 2010

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

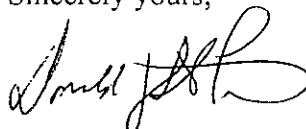
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Donald J. St. Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: syngo.plaza

Indications For Use:

syngo.plaza is a Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital medical images.

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Prescription Use X AND / OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE) CIUD

[Signature]
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K093612